



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,559	10/24/2003	Andrew W. Stamford	CN01472KB	9131

24265 7590 02/17/2006

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER
----------

CHANG, CELIA C

ART UNIT	PAPER NUMBER
----------	--------------

1625

DATE MAILED: 02/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,559

Applicant(s)

STAMFORD ET AL.

Examiner

Celia Chang

Art Unit

1625

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-8,17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10,12,15 and 16 is/are rejected.
- 7) ☒ Claim(s) 1-3,5,9,11,13,14,20 and 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's election with traverse of group I, compound of page 3 on pages 98-99 as the species in the reply filed on Nov. 30, 2005 is acknowledged. The traversal is on the ground that "Applicants are puzzled by the restrictions of the claims by the Examiner and believe that claims 1-21 form part of one and the same invention". This is not found persuasive because there is no reason to be puzzled since applicants have *already received an issued patent* to the group II invention.

The requirement is still deemed proper and is therefore made FINAL.

Based on the election, claims 2-3 and claims 1, 5, 9, 11, 20 and 21 reading on X and Z are N, g=0 compounds are prosecuted. Claims 10, 12-16 being drawn to method of using the elected compounds can be prosecuted with the elected compounds i.e. a rejoinder. Therefore, the restriction between group I and IV has been withdrawn.

Claims 4, 6-8, 17-19 and the remaining compounds of claims 1, 9, 11, 20-21 being drawn to the non-elected invention are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 10, 12, 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds having Y5 receptor antagonistic activity being useful in treating obesity or diabetes, does not reasonably provide enablement for the claims scope. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to treat all metabolic disorder or eating disorder the invention commensurate in scope with these claims. This is a scope of enablement rejection.

Initially, applicants attention is drawn to the term "metabolic disorder" is not limited to diabetes or hyperphasia. Please note that all diseases are metabolic disorder from vitamin deficiency to CNS neurotransmission pathology because a disease or disorder is a condition wherein the normal homeostasis of metabolism is disturbed i.e. metabolic disorder. The instant claimed compounds with limited Y5 antagonistic activity as described in the specification lack descriptive support for the scope of the claims encompassing *all* disease or disorder. Further, while Y5 receptor antagonists can be used to treat hyperphasia, thus, decrease food intake, such description can not support the claimed scope of treating all eating disorder which encompassed

Art Unit: 1625

both over eating, i.e. hyperphasia and bulimia or anorexia. As a matter of fact the compound which reduces hyperphasia i.e. over eating, given to a bulimic patient would be detrimental.

It is unclear what is the scope of claims 15-16, is the obesity resulted from type II diabetes, insulin resistance, hyperlipidemia and hypertension or is type II diabetes, insulin resistance, hyperlipidemia and hypertension resulted from obesity? The scope of this claim lacks descriptive support. There is no antecedent basis for the relationship among type II diabetes, insulin resistance, hyperlipidemia and hypertension and obesity or any description of how treating one can be connected to treating another.

3. Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what is the scope of claims 15-16, is the obesity resulted from type II diabetes, insulin resistance, hyperlipidemia and hypertension or is type II diabetes, insulin resistance, hyperlipidemia and hypertension resulted from obesity? The term "associated" renders the claims indefinite since how was the disorder or symptoms being associated and how does treating one will result in treating another cannot be ascertained.

4. Claims 1, 5, 9, 11, 13-14, 20-21 are objected because they contain the nonelected or allowed subject matter but would be allowable upon incorporation of the elected subject matter, i.e. incorporate the limitation of claims 2-3. Claims 2-3 are objected to because they are dependent on a non-allowable base claim but would be allowable if rewritten in independent forms.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Art Unit: 1625

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Feb. 14, 2006

  
Celia Chang  
Primary Examiner  
Art Unit 1625